

USSN 10/511,115 filed 23 June 2005
Atty. Docket No. 1103326-0781
Page 2 of 14

RECEIVED
CENTRAL FAX CENTER

JUL 18 2008

Amendments to the Claims

The following listing of claims will replace all prior versions and listings of claims in the application.

1. (Canceled)

2. (Canceled)

3. (Currently amended) An aqueous film coating polymer dispersion for pharmaceutical formulations, wherein the aqueous film coating dispersion is:

- = prepared by polymerizing a mixture of monomers in water and in the presence of an emulsifying agent to form a substantially uncrosslinked copolymer, and wherein the aqueous polymer dispersion is
- = substantially free of residual emulsifying agent which is removed after the polymerization reaction, and

wherein the mixture of monomers comprises:

- = acrylic acid or an ester thereof in the range 40 to 80 % by weight;
- = methacrylic acid or an ester thereof in the range 20 to 60 % by weight; and
- = a polymerizable surfactant in the range 0.01 to 9 % by weight, and

wherein the percentages refer to the percentage amount by weight of each monomer in the sum of the monomer weights.

4. (Currently amended) An aqueous film coating polymer dispersion for pharmaceutical formulations, wherein the aqueous film coating dispersion is:

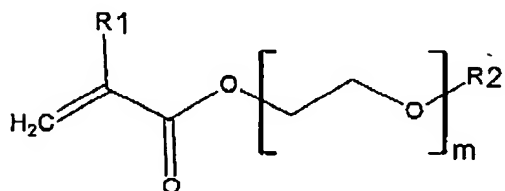
- = prepared by polymerizing a mixture of monomers in water and in the presence of an emulsifying agent to form a substantially uncrosslinked copolymer, and wherein the aqueous polymer dispersion is
- = substantially free of residual emulsifying agent which is removed after the polymerization reaction, and

wherein the mixture of monomers comprises:

- = ethyl acrylate in the range 40 to 80 % by weight;

USSN 10/511,115 filed 23 June 2005
 Atty. Docket No. 1103326-0781
 Page 3 of 14

- methyl methacrylate in the range 20 to 60 % by weight; and
- a monomer of the formula I and in the range 0.01 to 9 % by weight:



(I)

wherein m is an integer from 1-55,

$\text{R}1$ is hydrogen or methyl, and

$\text{R}2$ is hydrogen or a carbon chain having 1 to 20 carbon atoms,

wherein the percentages refer to the percentage amount by weight of each monomer in the sum of the monomer weights.

5. (Currently amended) An aqueous film coating polymer dispersion for pharmaceutical formulations, wherein the aqueous film coating dispersion is:

- prepared by polymerizing a mixture of the following monomers in water and in the presence of an emulsifying agent to form a substantially uncrosslinked copolymer, and
- substantially free of residual emulsifying agent which is removed after the polymerization reaction, and

wherein the mixture of monomers comprises:

- acrylic acid or an ester thereof in the range 40 to 80 % by weight;
- methacrylic acid or an ester thereof in the range 20 to 60 % by weight; and
- a polymerizable surfactant in the range 0.01 to 9 % by weight, and

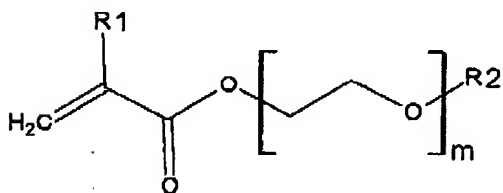
wherein [:] the percentages refer to the percentage amount by weight of each monomer in the sum of the monomer weights, and the emulsifying agent is an emulsifier with a molecular weight lower than 15 kD; and

~~the aqueous polymer dispersion is substantially free of residual emulsifying agent which is removed after the polymerization reaction.~~

USSN 10/511,115 filed 23 June 2005
 Atty. Docket No. 1103326-0781
 Page 4 of 14

6. (Currently amended) An aqueous film coating polymer dispersion for pharmaceutical formulations, wherein the aqueous film coating dispersion is:

- prepared by polymerizing a mixture of the following monomers in water in the presence of an emulsifying agent to form a substantially uncrosslinked copolymer, and
- substantially free of residual emulsifying agent which is removed after the polymerization reaction, and wherein the mixture of monomers comprises:
 - ethyl acrylate in the range 40 to 80 % by weight;
 - methyl methacrylate in the range 20 to 60 % by weight; and
 - a monomer of the formula I and in the range 0.01 to 9 % by weight:



(I)

wherein m is an integer from 1-55,

R1 is hydrogen or methyl, and

R2 is hydrogen or a carbon chain having 1 to 20 carbon atoms, and

wherein [:] the percentages refer to the percentage amount by weight of each monomer in the sum of the monomer weights, and [;] the emulsifying agent is an emulsifier with a molecular weight lower than 15 kD; ~~and~~

~~the aqueous polymer dispersion is substantially free of residual emulsifying agent which is removed after the polymerization reaction.~~

7. (Currently amended) An aqueous film coating polymer dispersion for pharmaceutical formulations, wherein the aqueous film coating dispersion is prepared by polymerizing a mixture of monomers in the presence of water to form a substantially uncrosslinked copolymer, and wherein the mixture of monomers consists of consisting:

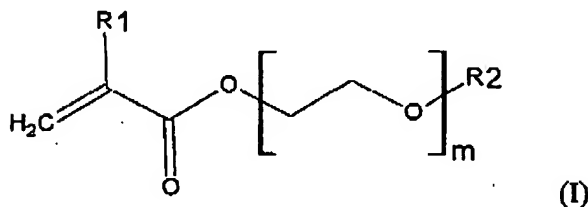
- acrylic acid or an ester thereof in the range 40 to 80 % by weight;
- methacrylic acid or an ester thereof in the range 20 to 60 % by weight; and

USSN 10/511,115 filed 23 June 2005
 Atty. Docket No. 1103326-0781
 Page 5 of 14

= a polymerizable surfactant in the range 0.01 to 9 % by weight, and
 wherein [:] the percentages refer to the percentage amount by weight of each monomer in the
 sum of the monomer weights, ~~and the monomers are polymerized in water.~~

8. (Currently amended) An aqueous film coating polymer dispersion for pharmaceutical formulations, wherein the aqueous film coating is prepared by polymerizing a mixture of monomers to form a substantially uncrosslinked copolymer, and wherein the mixture of monomers consists of consisting:

- = ethyl acrylate in the range 40 to 80 % by weight;
- = methyl methacrylate in the range 20 to 60 % by weight; and
- = a monomer of the formula I and in the range 0.01 to 9 % by weight:



wherein:

m is an integer from 1-55;

R1 is hydrogen or methyl; and

R2 is hydrogen or a carbon chain having 1 to 20 carbon atoms, and

wherein [:] the percentages refer to the percentage amount by weight of each monomer in the
 sum of the monomer weights, ~~and the monomers are polymerized in water.~~

9. (Currently amended) A pharmaceutical ~~coating film coating~~ for coating a pharmaceutical dosage form, wherein the film is prepared by applying the aqueous film coating polymer dispersion according to any one of claims 3 to 8 to the surface of the dosage form and removing water from the aqueous film coating polymer dispersion to obtain the film.

USSN 10/511,115 filed 23 June 2005
Atty. Docket No. 1103326-0781
Page 6 of 14

10. (Original) A pharmaceutical formulation comprising:
- a) a pharmaceutical core comprising a pharmacologically active ingredient; and
 - b) a film coating comprising a film according to claim 9.
11. (Original) A pharmaceutical formulation comprising a pharmacologically active ingredient which is provided in a plurality of beads wherein each of the beads is coated with a film according to claim 9.
12. (Previously presented) The formulation according to claim 10 or claim 11, wherein the formulation is a controlled release formulation.
13. (Previously presented) The formulation according to claim 10 or 11, wherein the pharmacologically active ingredient has activity in the treatment of cardiovascular or gastrointestinal diseases.
14. (Previously presented) The formulation according to claim 13, wherein the pharmacologically active ingredient is a beta-blocking adrenergic agent.
15. (Previously presented) The formulation according to claim 14 in which the pharmacologically active ingredient is metoprolol or a pharmaceutically acceptable salt thereof.
16. (Previously presented) The formulation according to claim 15, wherein the metoprolol salt is the tartrate, succinate, fumarate or benzoate salt.

Claims 17-26 (Canceled)

27. (Previously presented) The aqueous polymer dispersion according to claim 4, 6 or 8, wherein m is an integer from 2-55 in the monomer of formula I.
28. (Previously presented) The aqueous polymer dispersion according to claim 4, 6 or 8, wherein m is 4, R1 is hydrogen and R2 has 13 carbon atoms in the monomer of formula I.

FROM 20 BUSINESS ROOM A

(FRI) 7.18'08 11:04/ST. 11:02/NO. 4864582090 P 7

USSN 10/511,115 filed 23 June 2005
Atty. Docket No. 1103326-0781
Page 7 of 14

RECEIVED
CENTRAL FAX CENTER

JUL 18 2008

29. (Previously presented) The aqueous polymer dispersion according to claim 4, 6 or 8, wherein m is 10, R1 is hydrogen and R2 has 11 carbon atoms in the monomer of formula I.

30. (Previously presented) The aqueous polymer dispersion according to claim 4, 6 or 8, wherein m is 25, R1 is hydrogen and R2 has 18 carbon atoms in the monomer of formula I.

31. (Previously presented) The aqueous polymer dispersion according to claim 4, 6 or 8, wherein m is 1, R1 is methyl and R2 is hydrogen in the monomer of formula I.

32. (Previously presented) The aqueous polymer dispersion according to claim 4, 6 or 8, wherein m is 9, R1 is methyl and R2 is hydrogen in the monomer of formula I.